The ISO 9001: 2000 standard

Legitimization, fashion or actual quality improvement?

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1 Introduction

The concept of quality has been one of the most dominating and influential "meta-ideas" globally over the last twenty years, invading both the private and the public sector (Czarniawska & Sevón, 1996). The theme of this thesis is an approach named ISO 9001:2000 standard. The approach is in this setting the basis for a managerial system called internal control. In the US and continental Europe this approach is used across many sectors. Using a rational perspective organizations only exist because they are efficient. Efficiency creates legitimacy and is what keeps the firm alive. They reorganize and restructure themselves according to measures that are considered as the most efficient way of achieving the current organizational goal at that specific point in time (Røvik, 1998). The subject in this thesis is a public Norwegian hospital. The hospital face pressure for efficiency from the regional health authority and the ministry of health, at the same time they both desirer, and the hospital aspire for higher quality of care. Akershus university hospital health trust has decided to commence on becoming ISO 9001:2000 certified, one department is certified and several departments is underway. The main research question in this thesis is:
Why did Akershus University hospital decide to commence on an ISO 9001:2000 certification process?

New institutional theory presents a symbolic perspective; here organizations are seen as effective by accommodating and adapting to environmental demands and socially constructed demands. Organizational recipes are implemented by organizations not only on basis of efficiency, but also due to legitimacy. Organizational recipes can be adapted in different ways and not necessarily lead to much change in behavior. The new institutional theory anticipates that organizations implement new structures to reflect institutional myths rather than to solve instrumental tasks (Meyer and Rowan, 1977). Little evidence is presented that support positive effect on either quality or efficiency due to ISO 9001:2000 (Kunnskapsenteret, 2006). The public hospital trusts are under pressure to provide safe and high quality services, this implies a measurement of performance and systems to improve

quality of care, but they also faced pressures for higher efficiency and cost control. There is not much evidence of a positive relationship between quality and financial performance (Ittner and Larcker, 1998). The relationship between quality and economics is a complex one and thus systems and initiatives seeking to visualize such relationships by integrating measures of quality, financial results and resource utilization this imply a risk of creating ambiguity, fuelling conflicts and reducing the possibilities of organizational action (Brunsson, 1989, 1990). According to Meyer and Rowan (1977) organizations incorporate popular structures ceremonially as a formality without questioning the effects. The rhetoric appellation of the structure focuses on rational motives, but the diffusion of the structure appears to be driven by more symbolic forces (DiMaggio and Powell, 1991). The Norwegian knowledge center for health services presented a literature review on the basis of ISO 9001:2000, here the conclusion is that; the effects of certification and accreditation are unclear and largely unknown. Why are then an increasing number of health organizations engaging in it?

1.1 Research objectives and questions

This thesis aspires to give some explanation to why more and more actors in the Norwegian health care are engaging ISO certification processes. Primarily I will use new institutional theory to analyze the way the organizational recipe is adapted. I seek to scrutinize to what degree legitimacy is the motivation for engaging in ISO 9001:2000 certification. Furthermore study how the ISO 9001:2000 standard is adapted and implemented, and investigate the coupling of organizational structures and behavior. I will also study to what degree the ISO standard based quality system has resulted in a change of behavior. Last I also want to describe certification and accreditation as means of achieving quality of care in the Norwegian hospital setting.

The main purpose of this thesis is to investigate if neo institutional theory can shed new light on the ISO 9001:2000 standards function in regard to effectiveness and legitimacy. I seek to investigate the spread of the ISO standard, as it can be defined as an organizational recipe. The study deals with motivation, process and end result of accreditation or certification in regards to behavior. Often an instrumental perspective is applied in analysis of implementation of organizational recipes. This thesis uses a neo-institutional perspective, following Mayer and Rowan. They put forward a hypothesis that organizations in order to

avoid conflicts will decouple structural elements from the day-to-day activity. Friedland and Alford (1991) talks about how every organization are simultaneously exposed to many institutional demands that partially are inconsistent. Different groups of actors, both internal and external, may have different demands to organizational structure and procedures. As a response to this the organization try to mirror inconsistent norms, this means that different pictures of oneself is reflected to the different groups of actors.

A common way of explaining reforms is applying an instrumental perspective, where the lack of performances on standards, procedures or systems are described and evaluated along the axis of implementation or rather lack of implementation. I will use an institutional perspective including decoupling as a central concept. Brunsson (1989, 1990) and Røvik (1998) describe decoupling in different ways. This thesis explores and predicts some concrete findings, based on new institutional theory in general, and use in the interpretation of the three case studies at Akershus University hospital.

1.2 Theme

1.2.1 Development of quality concept and approaches

We can talk about one internal and one external development in quality concept and approaches when it comes down to the health care sector.

1.2.1.1 Internal development of quality

Internally the scientific developments in medicine resulted in better and more suitable means of delivering ever increasingly complex interventions with better prospects for patients. Or as Sir Cyril Chantler said: “Medicine used to be simple, ineffective and relatively safe. Now it is complex, effective and potentially dangerous” (Cited by Moss, 2003). The earliest direct quality work in the health care sector was conducted by Florence Nightingale in 1859 (Sprague, 2001) . She pointed to the high death rates, and argued that they to a large degree were preventable and created the world’s first performance tables for hospitals. In 1914 the American physician Codman engaged in analysis of surgical outcomes. He argued that studying the healing process for a patient would provide insight into better procedures and practices when it came to surgery (ibid). The outcome of Codman's initiative illustrates the difficulties of standing up to the reigning medical rationalities, like Semmelweis argument for

hand-washing back in 1844 in Vienna, Codman's call fell upon deaf ears and the reaction of his peers where to expel him as the president for the local medical society. In the mid 20th century the internal development manifested as emerging semi-professional groups gained recognition and power. In medicine the bloom of the large-scale studies of outcomes and reviews of studies, called meta-studies, laid down a fundament for stronger focus on scientific evidence on effects. This was the basis for evidence-based medicine. Physicians like Archie Cochrane initiated this movement and it has had effects on central aspects of quality, such as the burden of complications and survival rate. The economic burden to the society resulted in intervention by the politicians in the 1960s and 70s, laying down demands of economic control, increasingly focusing on equity and later quality.

1.2.1.2 External development of quality

Externally quality theory and approaches go back to the guildhalls. Their standards where made in regard to materials, products and practices. As industrialization emerged, the concept of specialization and the need for supervisors was created (Mouradian, 2002). The pressure towards profit resulted in the collapse of internal supervision and the separate inspection department with a "chief inspector" emerged. As industrialization paved the way for increased overall wealth, quality became more important than just defect prevention. The economic demand for more reliable products fueled the innovation of theory to enhance and secure high quality (ibid). The First World War resulted in an increased focus and sophistication of quality approaches, as standards and quality became important for the war effort. Statistical theory did in the 1920's create the fundament for effective quality control and in 1924 Shewhart developed the first modern control chart (Ibid). Statistical process control (SPC) theory emerged based on the control chart and was further developed by Deming, Dodge and Romig (ibid). SPC did not become common across industries until after the Second World War. Then the Japanese successfully adopted and adapted the statistical process control and turned a reputation for cheap imitation products and an illiterate workforce into a success in many markets, with a signature of high quality and low price. This was mainly due to the work of "quality-gurus" such as Juran, Deming and Feigenbaum (Imai, 1986).

Feigenbaum presented in 1969 the concept of "total quality". The concept referred to large-scale issues such as planning, organization and management responsibility. Another Guru, Ishikawa explained the "total quality control" in a Japanese setting (Ishikawa, 1985). He

pointed out the company´s wide quality control and described how all employees, from the top management to the workers, must study and participate in quality control. Quality theory did not manifest in the West until the early 1980's, when companies introduced their own quality programmes, as an initiative to counter the Japanese success. The concept Total Quality Management (TQM) emerged out of this and became a large trend across different industries.

1.2.1.3 The melting of internal and external developments on quality

The internal and external development of quality concepts and approaches melted together in the health care sector in the late 1980s. New Public Management (NPM) presented itself as a reform wave in many countries during the 80s. NPM brought private sector approaches and concepts of management, control/steering and quality into the health sector. TQM was perceived as a modern and rational formal structure, it took the form of a rational myth. Because of this many local quality initiatives where started in Norwegian health care based on the TQM philosophy during the 1990s. Most hospitals implemented TQM without ever asking for/or receiving real proof as to whether or not the TQM was positively correlated with efficiency, quality of care or any other goal function they had. The TQM phenomenon can also be seen as a result of the diversity of signals from the environment and the different "producers" of rationalized myths. The "producers" are patient organizations, universities and educational system in general, the legal system, the different professions, ideologies, technologies, regulatory structures, verification and accreditation bodies, governmental endorsements, recommendations and requirements. The wide range of sources can result in contradicting and inconsistent expectations, demands and signals from different actors in the organizational environment. Meyer and Rowan propose that such conflicts could be resolved by decoupling (Meyer and Rowan, 1991). Without or with few inspections and evaluations, the organization is able to shield the operational activity and buffer for the environment without loss of legitimacy. The concept of TQM faded away as one failed to identify gains and the focus shifted, as the government introduced more structural means and demands for quality. That is why we observed a shift from process-oriented efforts such as TQM and internal control, towards performance measurement efforts and regulatory compliance. Søreide describes how the national quality indicators imply steering of public trusts because indicators include an indirect way of steering, a mechanism often observed in the NPM (Søreide, 2006). In the past five years several reforms have been introduced in Norway.

Many of these have had an ambition to change the way managerial and professional actors operate and behave through NPM like mechanisms.

1.2.2 The Norwegian quality system

In the beginning of the 1980s a focus on service was manifesting in Norway. Quality was first linked to standardization and specification of technical medical supplies and machines (NOU 8, 1982). Throughout the 1980s an understanding of quality both in regard to technical equipment and health services in general was linked to organizational conditions, such as wrong use of equipment, wrongful administration of medications, infections and other complications, poor coordination and collaboration. During the 1990s the central health authorities took charge of the quality efforts. The further development had a dual characteristic; first through heighten governmental demands through regulations, secondly through strategy plans. Norway has a tradition for achieving policy goals through regulatory means. There is a vast set of regulatory demands the health care sector is faced with. In 1994 Norway got the internal control act demanding the establishment of an internal systematic review in all organizations. The compulsory internal control is linked to the health and safety regulations and other regulations and demands for each sector. Other initiatives to increase the quality of care have been marked measures such as free choice, having roots in both consumerism and marked theory. National health registers, quality indicators and compulsory quality work education in the post educational programs for health care workers.

1.2.3 Internal control and ISO 9001:2000

The difference between the concepts of a quality system and internal control is a subject for discussion. Both are based on systematic procedure evaluation, control and documentation. They both desire to be preventive, meaning that they are to reduce consequences, improve learning, and hopefully prevent errors and unwanted incidents altogether. A quality system shall furthermore also ensure that the given production process happens according to defined standards, in a timely fashion and is resource effective. A quality system is completely voluntary whereas internal control is mandatory. The main reasons for establishing a quality system is to ensure or strengthen competitive advantages and/or improve the process of production. A quality system can be formalized by being build after a standard, in this case ISO 9001:2000 and certified by an external authority. The main idea in internal control is that fulfilling regulatory demands can prevent negative outcomes, incidents and errors. The regulatory demands must be seen as a minimum and thus it is natural for a quality system to

extend further. This creates two sets of demands, the demands set by society in form of regulations and the demands set by the organization itself in regard to quality. The background for the regulation of internal control in 1994 was an acknowledgment that few organizations related to the given regulatory demands in a sufficient and efficient way. The regulation clarifies and specifies the demands and brings forward an active approach to responsibility and accountability through external supervision. It is necessary for internal control to function so that the leadership could put down clear objectives and establish routines and procedures to meet them. A quality system extends further than internal control. The ISO 9001:2000 standard defines how to build and structure quality management systems.

1.2.4 ISO 9001:2000

ISO is an acronym for International Standardization Organization. 9000 are the serial number on several standards that entails construction, use and revision of quality systems. The standard is in use in 149 countries. The use of ISO 9001: 2000 in health sector is moderate. A quick search on the Internet shows that in most European countries only a limited number of hospitals have obtained an ISO certificate. In Norway three hospitals are certified: Sykehuset innlandet: Kongsvinger (2002), Oslo Hospital (2002) and Innherad Sykehus (2005). The ISO standard has been updated since the early 90s when it was introduced to the health sector. In Norway the accrediting body is Norsk Akkredetering, which is a part of Justervesenet, a governmental organ under the Ministry of Trade and Industry. There are four certifying bodies licensed by Norsk Akkredetering (Arntzen and Mikkelsen, 2005). The revision in 2000 is the most important. Many countries have developed a national variant of the standard, the Norwegian is called NS ISO 9001:2000. The theoretical components of the standard are similar to other quality approaches such as Total Quality Management, Continues Quality improvement and Quality Assurance. The main difference is the structure. The ISO standard does not define quality, the organization does, and however the guideline gives the structure for the development and maintaining of a quality system. The ISO standard has a clearer defined functional application and has few sophisticated quality methods presented as a mandatory in a predefined package. The standard itself is updated and maintained by an international committee (ibid). The newest version is the ISO 9001 and was presented in 2000. The standard is a combination of eight components. The ISO 9000 series of standards explains quality concepts and contain basic definitions of quality. The ISO 9001 standard puts forward demands for how the establishments manage and structure quality systems to prevent errors and incidents.

1.2.4.1 Accreditation and certification

Accreditation means that standards are met and is a procedure where an external authority gives a formal recognition that a department can exercise a specified task or procedure, or a recognition of demands to competence and execution of a specified work procedure in accordance, with a given standard (ibid). The tasks are specified in detail and worked through by an accrediting body. The accreditation system covers and complements many of the demands in Norwegian regulation. Certification is a description from an independent body that the quality management system meets the basic structural demand and has been functioning for minimum 6 months. That a department or hospital is certified means that the activity is conducted in compliance with demands in both health and supervision regulation, further also owner demands, internal demands and customer demands.

1.3 Setting

My thesis work is conducted at Akershus University Health Trust. The study is presented as a master thesis. The thesis has received 20 000 NOK in form of a student grant form HORN. This thesis is produced in combination with an internship at the department of health economics and management at the University of Oslo in a project on change management in collaboration with Sintef.

1.3.1 Akershus University Health Trust

Akershus University Health Trust offers holistic services within common specialties of somatic and psychiatric illnesses and diseases. The health trust is a gathering of the main hospital in Lørenskog, Stensby hospital in Eidsvoll, Lillestrøm hospital and district psychiatric policlinics and children and youth psychiatric policlinics in Jessheim, Lillestrøm and Grorud. The trust manages a budget of 2,5 billion NOK, have 4200 employees, treat approximately 53 000 in bed patients and have 150 000 policlinic consultations (ahus.no).

The trusts main responsibilities are health services, research in the associated field and teaching tasks aligned with the University of Oslo. The Trust is one of six university hospitals in Norway. Quality is one of the five main goals in the strategic plan for the regional health authority; Health East for 2005-2008. A main element in this is the development of a holistic quality system based on ISO 9001:2000 in the underlying trusts. At Akershus University

hospital at present (February 2006) only the department of immunology and transfusion medicine is ISO certified.

1.3.2 The department of immunology and transfusion medicine

The department is supplying a product vertically throughout the hospital and delivers services to outside users such as medical centers. Blood handling starts with voluntary donors and has many end stations applications, and users. Production of blood related products and a testing is the main activity. The staff consists of bio-engineers, medical doctors, nurses and technical personnel.

1.3.3 The department of microbiology

The department handles a wide vary of array of tests. The medium is different and consists of everything from every ting from mouth and throat swipes to blood. The microbiological department is supplying a product vertically throughout the hospital and delivers services to outside users such as medical centers. The staff consists of bio-engineers, medical doctors and technical personnel.

1.4 Sequences and content

I have now in chapter one given a short introduction of the thesis theme. I will in chapter two elaborate on the method concerning the selection of study design, informants and different aspects of conducting the study such as, research effects, bias, and ethical considerations Chapter three presents the choice of theoretical perspective. Chapter four has been named is named case studies; it presents the data from the interviews conducted, observations and the story of each case. In chapter five theoretical themes and the case studies are discussed. Chapter six presents the conclusion and sums up the findings.

2 Method

2.1 Qualitative method

In new institutional theory one is concerned with how and why institutional demands for reforms manifests itself in the organizations environment. This involves how the reforms are introduced, translated, adapted, used and what effect they have in the specific institution. To measure organizational effects it creates major methodological challenges.

2.2 Selection of method

Patton (1990) put forward two paradigms: one logic-positivistic paradigm with emphasis on quantitative/ experimental methods to test hypothetic- deductive generalizations and one phenomenalistic paradigm that focus on qualitative/naturalistic methods to understand human experiences in specific relations. There are according to Patton (2002) three types of qualitative methods: open in-depth interviews, obvert observation and document analysis. In this thesis I have chosen an open in-depth-interview, semi structured with open questions to investigate the informants experiences, expectations, meanings, feelings, and knowledge. One advantage with a face-to-face interview is the nonverbal information it gives. This makes it easier to pick up on an emotional concerns the informant may have regarding to the theme of the interview, weather the informant is experiencing a feeling of stress or does not understand or is unable to relate to the questions. This situation makes the researcher more able to react and adjust the questions in order for the respondent to understand and talk freely. The open interviews strengthen the researchers control over the interview situation and usable respond rate. Furthermore the flexibility makes it easier to allow for the respondent to lead the conversation. Disadvantages with the method is that it is resource demanding, that the data analysis is time consuming and has a knowledge threshold, and the risk for bias due to the researcher.

Open in-depth interviews can be classified in to sub categories. I have chosen a format based on the naturalistic interview. Here one assumes that there is a social reality that is objective, that can be described and that the informants through the interview can make accessible in the process of research. The interview must therefore be shielded from the opinions of the one that conducts the interviews. The strength of this method is the flexibility, it can target a complex innovation like the quality system based on ISO 9001:2000. It is especially good for

few subjects and provides rich and detailed information. The method is capable of highlighting some fundamental processes of motives, adoption and change.

2.3 Selection of informants

The hospital is undergoing a major change. The organization has during this period a project administration along side the normal line administration. I selected the project manager for the ISO 9001:2000 and had preliminary contact with her. She gave me insights into the status quo of the organization. Since I wanted to use a time line in the hypothesis I asked for potential department that could fit into the category early adopter and late adopter. Based upon her insight I was able to find the department of immunology and transfusion medicine, an early adaptor and the department of microbiology that started the efforts at the same time as the rest of the organization. I decided to use two departments that were similar in structure and function; both departments selected are laboratory departments.

All informants from the two departments are bio-engineers. This is both an advantage and a disadvantage. It is an advantage since the realities experienced is professionally equal and that it might make the analysis easier. It might be a disadvantage, as it does not give an insight into the full clinical aspects that a hospital wide quality system is faced with. It might over focus on the professional reality of the group selected. I feel that major theoretical aspects were not lost due to this selection. At the two departments I decided that selecting one in a managerial position and the quality manager, and one floor worker could be sufficient. A total of five informants from the two departments and one from the project organization were interviewed. This would be a manageable group considering the size of the thesis and its objective.

2.4 Interview behavior and research effects

2.4.1 The relation between researcher and informant

The relation between the researcher and the respondent is not equal; it is the researcher who is conducting the interview that is the dominating part. This can influence the data, if the researcher unknowingly communicates his or her expectations or that the informants unknowingly or deliberately answer according to the perception of interest the respondent has

given. Such an imbalance was taken into consideration when time and place for the interview was conducted. In interviews where one interviews leaders, like I did, this imbalance might be reverse, something that might cause problems in steering the interview. Leaders are used to be in charge and often take the lead because of personal needs. To take this into consideration I tried to be brief in the beginning, to the point in the main body and consolidating at the end of the interviews. To the extent someone hijacked the interview I found it interesting as his or her agenda where shed light upon. All of the respondents gave valuable insight and information. They where enthusiastic and talked continuously and did not need much encouragement.

2.4.2 Selection of research role

During the interviews I chose to use the perspective Patton has called "Being-in" (Patton 2002). This perspective fits well with the intentions of the naturalistic interview. It consists of diving into another world, listening closely, openly and forgetting one owns views and reactions. Throughout the cores of the interviews I therefore tried to come across as positive and sympathetic, without giving away any expressions for what I may have thought about the questions. Patton (2002) states that full objectivity is not possible and that it therefore is important to be aware of the prior knowledge one has. The goal is to have an in-depth discussion and therefore a balanced open and reflected view on the role one self is playing.

During the interviews the depth was more or less consistent, the same goes for the need for follow up questions and so on. I gave both questions and key words to start the conversation. I tried to keep a balance between follow up questions to cover interesting or uncovered areas, and letting the informants lead the discussion. Sometimes I needed to put my questions into perspective for the informants, so that they would not seam so blunt, I did not plan this, but from time to time I felt like it was necessary to keep the respondent from "claming up", the number of times this happened varied across the sample.

2.4.3 Interview behavior

In the naturalistic interview it is especially important that the researcher try as hard as possible not to influence the informants, both in the preparation and the conduction. This so no wrong, partial or skewed information about the reality is passed along in the interviews. Throughout the whole process one therefore needs to keep this in mind. Such research effects might be nonverbal or maybe rather in the way one asks the questions. Such elements are

linked to asking to many questions at one time, asking one question that consist of many questions, leading questions, stressing that the question is not that important, being one sided in follow up questions, or yes or no answers. Yes or no questions do not invite the respondent to communicate, such questions rather shut down communication.

Patton (2002) stresses that one should not give into ones initial prerequisites on classifications, connections and patterns early in the process because they might result in the researcher becoming less open, on might lose/select out vital information due to the initial gut felling and insight. In the interviews it is the informants experiences, feelings and reflections that one seeks to gain access to. The behavior the researcher has therefore needs to be such that one do not influence the informants views or interpretations, the technique of conducting such a interview demands practice and such practice did I not poses. So I was totally depending on preparation and guidance from more experienced researchers.

According to Patton good interview behavior includes an emphatic and sensitive attitude that also is neutral, respectful and open. One should also keep the knowledge one may have on the field to one self and stray away from any polemic what so ever. The purpose with good interview behavior is to build up a close relationship on trust. This is important because the goal is to get the respondent to present his or her insight and reflections. Trust takes time to build up and can in a fresh relationship easily be torn down. Another important feature is that the researcher must keep a professional distance to the subject; this is vital for maintaining the analytical abilities. Evaluating ones position along this axis is important at all times.

2.5 Data analyzes

2.5.1 Process of analyzes

The interviews where taped and transcribed. But the aim of the study is not to produce transcriptions. The five interviews were conducted in the period from mid December to January. To rule out any technical malfunction, I used two recorders for each interview. The transcription where written out in Norwegian and only the selected quotations that I decide to use where translated to English. The translation was done through a process where two independent bilingual Norwegian-English persons first where given the text and asked to translate-it from Norwegian to English and then I switched and asked the other person to

translate it back into Norwegian. Then a comparison was made and corrections applied until the text matched within a margin of error, more based on meaning than words. The transcriptions functions are to aid the process by being a tool. To preserve the intention data the interviews must be transcribed as accurate as possible, without any interpretation from the researcher. To preserve the respondent's language and meaning all the interviews where carefully transcribed. Straight after every interview I also noted down reflections about the interview. The interviews gave a lot of information, the transcriptions where time consuming and the concluding notes where long. I used an external person to transcribe and I listened through the recording and read the text simultaneously. I found that the differences were not in the meaning but sometimes phases, where non-meaning words like," jaha"," hum" and such, mostly uttered by the researcher was not transcribed.

2.5.2 Analyzes

In the analysis of the interviews the data and theory is connected. The analysis of the interviews is to move from a describing to interpreting. Interpreting is to use the ex ante knowledge we have from theories to systemize the data. Using a hermeneutic setting for analyzing data means that one accept that there might be many different ways to interpret the meaning in the data. The process of analysis gives the data a link to theory, this happens through interpretation of the words the informants have used and uttered and placing them in theoretical and contextual categorizes.

Through the informants I hoped to get an impression of how on how they viewed the ISO standard and what was common and what was less common perceptions on legitimacy and strategic reasoning behind adoption. I searched for heterogeneous patterns and used the predictions made in chapter two as markers in analyzing the data material. Analyzes of data started by splitting the data up into manageable and thematic parts. Then I organized the data through the use of diagrams, matrix and summaries according to topics. The transcriptions were cut into small segments, categorized and put into labeled plastic folders. I created based on the theories and the interviews some categories. These I used in the analysis to find frequency and extent of the chosen concept or theories. The different categories was then gone through, evaluated, corrected for size by theme and meaning, compared, put into matrixes and diagrams while searching for patterns and trends that could give basis for conclusions. The analysis was made based on an ad hoc method of categorization, compressions and interpretations.

2.6 Quality of the study

In modern science concepts like validity, reliability and generalizability are important but also controversial in qualitative mythology. I decided to use them and therefore I will first clarify my meaning by the concepts and then the application of them.

2.6.1 Reliability

Reliability is related to the consistency of the data. Problems related to reliability might be leading questions, when it is not a conscious part of the interview tactics, and thus might influence the results. This is along the lines of accidental measurement errors. Questions about the reliability of a transcription are often raised in interview research. Technically it is an easy thing to let two separate persons transcribe the recording, and then compare the words that are different, and thus make a quantifiable ratability cheek. There is always an element of interpretation involved in transcribing a recording and thus a question for reliability. However the transcribing is only a tool to aid the process of analysis, and I tried to strengthen the reliability by reading and listening over the material, further more I sent the entire transcription back to the informants so they could comment.

2.6.2 Validity

Validity is about verifying the projects focus, this means that I am examining what I want to study. In qualitative research one need to keep the focus on the validity in al phases of the study. It must be integrated in the research work. In qualitative methodology the validity is communicative and descriptive: It is highlighted by explaining the method, references, tools, processes and results (Kvale, 2001). Some apparent challenges are: the researcher can feel so familiar with the field that he or she fail to identify important information. The researcher can put to much emphasis on his prior knowledge, so much of the deviation may not get picked up. The researcher might also put to much weight on quotes from individual informants, as he group some as key informants. I have tried during this study to strengthen the validity by identifying and being aware of my prior knowledge and reflecting upon what it might mean for both the interview situation and the analysis. Emphasize what is my opinion and where it comes from and what is the opinion of the informants. The data is quality checked through validation by the informants in the interview and by the informants reading the transcription of the interview.

2.6.3 Generalizability

Kvale (2001) describes a trinity between validity, reliability and generalizability. The reliability in my thesis is linked to the "craftsmanship" of the research, specifically the questions, analysis, interpretation and presentation of data. Validity relates to actually measuring what one seeks to measure. In regards to generalizability I do not seek to construct a general transferable truth, this due to the complexity of the situation the subject is in. The "truth" presented in this thesis needs to be viewed as socially constructed, a presentation of a reality then and there, given the limitation of the thesis, the informants view of the world and my ex ante knowledge.

2.7 Ethical considerations

All research needs to have an open relation to the ethics of their actions and behavior. Important aspects of ethics in research are consent, confidentiality and trust. Furthermore the different research traditions have their own set of specific guidelines and practices. Participation in research is always voluntary, consent therefore means that the respondent has accepted enrollment in a project, given this it is necessary to have enough information on the study to make this decision informed. Information about the study was therefore given to the respondent about the frames of the study before they where asked to participate.

Confidentiality is linked to making the participants of the study anonymous so they cannot be recognized. I have used numbers and not names on the respective informants through out the entire process. It is for the respondent important that the meaning of the statement is preserved and not misused. The quotes are uttered in a setting. Therefore I have on some occasions called the informants back to clarify my understanding against the respondent's intentions. Conducting a naturalistic interview puts demands on the researchers neutrality. It demands that the researcher keeps a close relation, but not to close and that the transcription and translation is honorable, and that one places quotations in the same setting as they where uttered.

3 Theory

To study organizations and how they behave internally and externally we utilize organizational theory. This category of theories has its contributions from many disciplines such as sociology, psychology, political science, social anthropology, economics and management. Organizational theory has been classified into four different theoretical perspectives: rational, natural, open system perspective and new-institutionalism (Scott, 1992). This classification is not a dichotomy, but more a classification of historical origin, inherent value settings, focus and such. The perspectives are on collision cores on some subjects, overlap and complement one another on others. The four perspectives are not static and have evolved over time, and the popularity and status have differed. The perspectives give different angles of approach to guide and interpret empirical research. All the approaches contribute into understanding organizations. I have chosen to use new institutional theory because it may complement the mainstream of rational approaches already undertaken. I think it can contribute to the understanding in a wider sense off what the ISO standard is, the role it plays in the organization, how it is adapted and used and finally what functions it serves.

3.1 New institutional theory

New institutional theory has its focus on how values, norms and modes of rationality influence the way organized action unfolds (Scott, 1992). Cultural and normative structures such as an organization's environments and its formal governance structures are given value. Organizational structures and systems are seen as important even if their impact on participant behavior is low. The institutional frames is signaling internal meaning and rationality and exercising the compliance with wider belief and rule systems (Scott, 1995). 'Myths' are defined by Meyer and Rowan as "powerful institutional rules which function as highly rationalized myths" and are therefore taken for granted (Meyer and Rowan, 1991). Rationalized myths are stories constructed by the organization to conform the actual tasks the organization is supposed to serve. The stories serve symbolic purposes of reassuring influential actors and gathering the public support which the organization need. Røvik (1998) defines institutionalized standards as "a legitimized recipe on how to structure parts or elements of an organization". They inspire organizations all over the world to organizational change and reformation during the same period of time (Meyer and Rowan, 1977). An

organization perceives and reacts to signals about conformity and based on the societal environment and thus seeks legitimacy. The organizations formal structures may then be organized to reflect the rational myths in the external environment. The structures based on the rational myths can be organized in a ceremonial way. This means that they are not strongly related to the core activity within the organization. This allows the organization to buffer or hide the uncertainties of technical activities being performed within it (ibid.). New institutional theory can be defined in different ways, I have included a wide set of traditions to illustrate the grasp.

- Rational choice refers to analysis based on the assumption that decision-makers are rational, self-interested optimizers. (Public choice theory)
- Historical institutionalism prefers to study each case as a unique constellation of cooperating and competing actors shaped by unique historical backgrounds.
- Resource Dependence Theory (Pfeffer and Salancik, 1978). Resource dependence theory is somewhat integrated into New institutional theory. It uses similar concepts such as cooptation/buffering being almost the same as legitimacy/decoupling.
- Sociological institutionalism studies that put emphasis on the socio-cultural construction, to explain individual behavior within institutions.

The last segment includes the symbolic functions of institutional forms and the quest for organizational legitimacy as the dynamic behind the diffusion of managerial innovations or rationalized myths. Within the last position the behavior of individuals in organizations cannot be simplified into a small set of motivations in contrast to public choice theory where attempts are made based on assumptions about the individuals being rational, benefit-maximizing actors and so on. Behavior must be explained on a specific situation, with each context different (Scott, 2000).

3.2 Theoretical framework

3.2.1 Isomorphism

In any organizational field, organizations tend to become homogenous in both process and structure over time. Managerial innovations may be spread for performance reasons, but also for reasons not linked to efficiency. Innovations can be adopted for reasons of legitimacy and

reducing uncertainty by mimicking others, even though no evidence support a actual gain performance. Meyer and Rowan (1977) gave this account on the isomorphism:

"*Organizations are driven to incorporate the practices and procedures defined by prevailing rationalized concepts of organizational work and institutionalized society. Organizations that do so increase their legitimacy and their survival prospects, independent of the immediate efficacy of the acquired practices and procedures." (*Meyer and Rowan, 1977)

DiMaggio and Powell (1983) created the name and defined three sub-groups.

• Mimetic isomorphism- everyone else in the industry is doing it

• Coercive isomorphism- customers, suppliers, and regulators are starting to demand it.

• Normative isomorphism- it has become accepted practice or promote by certain professional groups.

Isomorphism can give grounds to some predictions of change at the organizational level that can be applied in the setting of this thesis. Coercive isomorphism gives a prediction that the greater an organization rely on or is being controlled by someone, the more it will imitate others. The more dominant or leading an organization is, the more others will imitate and replicate its solutions, structures and systems. Mimicking isomorphism can deduce a prediction that the higher degree of uncertainty is in a relation between process and outcome, the more an organization will imitate others it perceives as successful. The more diffuse the goals and standards an organization seeks to achieve, the more they imitate others it perceives as successful. Normative isomorphism gives a prediction that the more reliance on professional groups, the more the organization will converge in the field.

3.2.2 Legitimacy

The adoption of organizational recipes can be linked to rational or symbolic motives. DiMaggio & Powell (1983), emphasize the motive of organizational legitimacy over the motive of organizational efficiency. When forced to choose, organizations will select options that preserve and enhance organizational legitimacy. Legitimacy may undermine rationality, although the foremost reason for incorporating a new structure was originally fuelled by the efficiency paradigm (Brunsson, 2002). The institutional view emphasizes how legitimacy is perceived through a set of constitutive beliefs the cultural definitions determine what is considered legitimate (Suchman, 1995). Formal organizational procedures may serve symbolic purposes of legitimacy rather than substantive purposes of performance (Meyer & Rowan, 1977). Suchman (1995) categorize legitimacy in to three, normative or moral legitimacy, pragmatic legitimacy, and cognitive legitimacy. Legitimacy is in new institutional theory seen as a result of factors in the environment and changing situation there. Legitimacy

has its base in the normative and cognitive, and not seen as something one can control or influence.

3.2.3 Decoupling

Decoupling can be defined as a situation where organizations "...decouple elements of structure from activities and from each other" (Meyer and Rowan, 1977). Decoupling is a type of organizational behavior seeking to reduce conflicts and loss of legitimacy when control and coordination of activities appear. Decoupling results in changes in formal structures that are effective in terms of increasing the likelihood of survival. Decoupling as a phenomena are in institutional theory perceived as a expiration or lack of coherence between the demands and expectations that a organization are faced with and the structures and actions which are necessary for production (Meyer and Rowan, 1977, Brunsson and Olsen, 1993). The central hypothesis states that if new concepts are poorly adjusted or do not fit with the demands from the main operational activity, it will be decoupled from the daily activity. This means that the concept is a symbol that is not directed towards the efficiency, but legitimacy. Decoupling as a concept is used in many settings. There are studies on decoupling between internal structural units (Lawrence and Lorsch, 1967), between shifting internal constellations (Cyert and March, 1963) and between intentions, actions and decisions (March and Olsen, 1976). New institutional theory often describes a structural decoupling where formal structure is decoupled from actual actions in the organization. Bordering on rational choice, we often find behavioral decoupling, here the focus is on decisions, which often is unconnected to actions. Decoupling can be described as the process of disintegrating the structural elements of different parts of the organization in response to institutional pressures to comply with inconsistent norms (Meyer and Rowan, 1977).

As a means to gain legitimacy organizations may be persuaded by a rationalized myth and thus adopt an organizational recipe for a given structural characteristic. This is then a result of pressure for conformity and need for legitimacy rather than organizational efficiency. The organizational recipe holds no loyalty base other than their functional ability to gain legitimacy. The local belief in the organizational recipe may be vague at best, this since the workers do not view the organization in the same context, and further may also recognize the local practice of using it only for appearances. A dual set of practices thus is created the "formal" and the "actual." New employees and embedded consultants are the ones that

easiest observe this duality as the initial talk and descriptions slide over learning and observing the way things are really done in practice.

3.3 Literature review

Early research on organizational recipes and the spread and adaptation in organizations has primarily been qualitative and/or case-based. I will now go through some of these studies. Meyer and Rowan (1977) proposed that while organizations often adopt formal policies, plans, and programs that display conformity to socially sanctioned purposes, they may also decouple these formal structures from actual, ongoing practices in the organization to buffer internal routines from external uncertainties, thus enhancing flexibility while still maintaining legitimacy with important external constituents. In new institutional theory talk, decisions and action have a value in their own right. Talk, decision and action are three types of organizational output. They are not seen as necessarily subsequent steps in a process, where talk leads to decisions and decisions leads to action.

Organizations can produce divergence between talk decisions and actions because they are confronted with inconsistent demands from the environment. They not only have to provide good products and services, they also have to comply with institutional structures, processes and ideologies (Brunsson, 1989). The extent to which a public organization is satisfying the external demand to production is less observable compared to private organizations that work in markets. Departments may talk in one way and act in another to satisfy demands of the top management. Meyer and Rowan (1977) developed the decoupling thesis from qualitative work on educational institutions. Their research suggested that formally adopted standards and procedures, which appeared to address government mandates and community demands, were decoupled from the on-going routines of teaching and administration.

According to Brunsson and Olsen (1993), the decoupling of the formal structure and practical action explains the problem of getting public reforms to work as intended. It is argued that they may have an effect on a symbolic level but do not have any substantial effect on organizational practice. Abernethy and Chua (1996) described how decoupling the control systems used at different levels of the organization was a common solution to handle conflicting pressures in public sector organizations. Decoupling between action and corresponding effect means that decisions implemented on paper not necessarily manifest in

effect in practice. In a study of quality assurance in health care organizations in Sweden, Elingsdóttir (1999) describes how the work at two hospital departments was quite unaffected by an ongoing quality improvement program that was considered of great importance by the hospital management. Westphal, Gulati, and Shortell wrote an article called customization or conformity? In 1997, this article shows how early adopters of TQM to a larger extent customized TQM practices for efficiency gains, while later adopters gain legitimacy from adopting the normative form of TQM programs. The article used quantitative methods and was conducted across the population of American hospitals. Levin (2006) followed this way of thinking and thought and presented his contribution based on a collection of qualitative and quantitative methods in Institutionalism, Learning, and Patterns of Selective Decoupling: The Case of Total Quality Management. It adds to and refines our understanding of institutional theory, particularly the notion of decoupling based on the 1990s situation when TQM flourished in the hospital population. TQM and the ISO standard is not the same thing, but both are complex innovations and both deal with quality of health care services. The study examines decoupling across multiple dimensions of a complex administrative innovation, TQM. In this study they identify a pattern called *selective decoupling* by late-adopting hospitals. The study suggests that, when it comes to implementation *after* adoption, institutional forces create subtle but predictable patterns of selective decoupling. Levin (2006) found that in contrast to the more straightforward innovations studied in previous decoupling research; the opportunity for decoupling is particularly strong in the case of complex innovations.

3.4 The environment, rationalized myths, rationalities and logics

In organizational fields that undergo changes and reform efforts, there are conflicting and competing rationalities, and complex environments. Heterogeneous functions, tasks, professions, client groups, and organizational cultures are features of a hospital. The heterogeneity is reflected in different organizational principles and rationalities that are in simultaneous action. A change effort can disrupt and alter the balance between actors and their rationalities, leading to possible contradictions between democratic, administrative and professional rationalities. Institutionalized values like participation in decision-making (a democratic logic), are in conflict with and must be balanced against the need to control the organization (an administrative logic), and further the autonomy of the health care

professionals in their sphere (a professional logic). The different groups of actors perceive the demand for high quality health services differently.

Røvik (1998) states that there is many ways to view an organization. A wide spread belief is that formal organizations to a large degree is consistent," holistic" structures as a result of board members and other high placed hierarchy decisions creating a task oriented machinery. And where the components of the organization are put together due to logic. The knowledge that modern complex organizations are faced with competing organizational recipes suggests a different view towards the organization. As a hypothesis Røvik (1998) states that one can view the building and evolvement of an organization as being a result of different actors across the organization uncoordinated selecting from different sets of organizational recipes. Thus one can assume that organizations can present them self more as loosely coupled institutionalized components then homogenous "buildings".

All organizations have sector specific markings, behaviors, environments, cultures, contexts and conditions. Mintzberg (1979) have called hospitals for professional bureaucracies. One specific feature of the professional bureaucracies is complexity, both in regards to goal and performance. Work is coordinated through autonomous professional standardization of skill and but there is also an orientation against external solutions. This view makes hospitals operate with complex process of procedures, but at the same time they are stabile enough to be standardized. Different groups can have conflicting goals, and some times one group pursue multiple and conflicting goals. For hospital managers it might cost constraints and quality, accountability versus development and improvement. Accountability is gained thorough control, where as development often come out of a continuous trial and error processes. Clinicians' objectives and practices may be different from management's uttered goals for safety and quality.

3.4.1 Adoption and reactions

Akershus University hospital is undergoing a major change, it is moving into new physical buildings and at the same time undergoing a large-scale organizational restructuring. This further adds to the complexity the departments are faced with. Many new structural elements as well as procedures are introduced at the same time. New physical surroundings can in itself limit ones ability to function, and even the small things may become distracting to start with. Systems and procedures are not imposed in the same way, they are not an either or. There is a

continuum from not used at all to fully used and locally fitted to task. Systems and procedures describe and dictate behavior, but there are many ways to react and to handle these demands.

Organizational recipes, like ISO 9001:2000 can be viewed as a local reform. Organizational theory shows that there are many problems with implementing new reforms. Many reform attempts may just have been a waste of time and resources, and others may even have decreased the actor's capacities to act in a concerted and innovative way, as seen in the example of "organizational blockage", a situation with collapse in communication (Crozier, 1964). Systems may be perceived in many ways and this can strongly influence the initial reaction and final ability a system or reform has of steering behavior. Levay and Waks (2005) conducted a study where they described different professional responses to transparency efforts. Here they described that in some cases the professionals do become actively involved in assessment procedures by influencing the terms of evaluation, where by they attempt to promote the interests of their own profession, their specialty or their organizational unit, in other cases, professions react with resistance or decoupling strategies. While Søreide (1999) talks about how reforms may be rejected, either by veto-groups or by the professional system as a whole.

Brunsson talks about how decoupling of the formal structure and practical action explains the problem of getting reforms to work as intended. It is argued that they may have an effect on a symbolic level, but does not have any substantial effect on organizational practice (Brunsson and Olsen, 1993). The reform can be adopted according to Brunsson quite often in a passive, superficial way, as part of a windows-dressing strategy (Brunsson, 1989). Røvik on the other hand states that implementing a reform consist of a translation. The translation happens when reform ideas are transformed as they meet the organizational members and their local patterns of thought and action (Czarniawska and Sevon, 1996; Røvik 1998). According to Brunsson and Olsen (1990) resistance towards innovations, reforms or standards, can have many reasons, one of which is that the professionals feel a reform is built on the wrong premises, is contradicting or straightforward destructive for the institution. One solution to this can be that one displays an adjusted image externally, while one in reality sticks to the old norms, processes and systems. A institutional perspective on reforms do not state anything about what is right or what is wrong or which reform, innovation or standard is the best, it only gives express for a reform having resulted in change of behavior or if it has not. Oppose to

the instrumental perspective, in the new institutional perspective one can expect resistance against change in activities, new systems and introduction of organizational recipes.
In an institutional perspective the ability a reform or organizational recipe have to change the behavior depend on how well it fit in with norms and values in the institution. Thus reforms that do not fit will be met whit resistance (Brunsson and Olsen, 1990). The concept of institutionalization makes organizations stable and predictable and at the same time makes implementation of new recipes and reforms difficult. Thus from an institutional perspective reforms are easier to suggest and decide upon than to actually implement and see through (Brunsson and Olsen, 1990). Resistance against introduction of new organizational recipes can be met whit a different set of behaviors ranging from: adoption, compromising and challenging decisions too a pure blockage of the initiative. Decoupling is a concept in new institutional theory that often occurs in this type of situations. The resistance efforts towards change are by the professionals expected to manifest in statements and positions like the ones listed below:

- The organizational recipe is incompatible or is violating the professional norms, values and logics.
- It is hard to argue the need for the organizational recipe to different groups due to legitimacy.
- Disbelief in the capability of the organizational recipe to deliver according to the goal function, and a belief in the organizational recipe as not aligning with neither other organizational goals nor the goals of the professional group.

3.4.2 Brunsson and Røvik

Decoupling in new institutional perspective differ, being incorporated into organization of hypocrisy by Brunsson (1989), and being seen as a byproduct of the multi standard organization by Røvik (1998). Organization of hypocrisy targets the link between normative and cognitive organizational processes. Røvik view decoupling as a byproduct, where as Brunsson promotes it as a conscious decision. Brunsson position is that organizations decouple structural elements from daily activity to avoid conflicting demands. He expands this argument by stating that the institutional myths them self may be conflicting or inconsistent. Thus the organization will try to mirror different demands to different external and internal actors. Røvik states that this is a difficult thing to do, and that the risk for being exposed is large (Røvik, 1998). According to Røvik translation represent an alternative

concept and is not taking on a mask of decoupling. Translation of the organizational recipe relates to the organizational identity.

Brunsson and Røvik both present theories that can explain how modern organizations adapt organizational recipes and behave to signals in the environment. The two present concepts that in many ways are similar, but with different logics behind. Røvik states that organizations seek to incorporate many different organizational recipes and institutionalized standards, and thus decouple them from one another. Brunsson state that hypocrisy/decoupling is a way for organizations to create and maintain legitimacy in its organizational field, decoupling here becomes signaling one thing yet doing something else. The starting point for Røvik is inconsistencies between organizational recipes in the organization, where the starting point for Brunsson is inconsistencies in between the organizations goals.

3.4.2.1 Brunsson

Brunsson sees decoupling as a characteristic of the organization of hypocrisy. He describes a type of behavior in the organization where the goal is to gain legitimacy and support from the environment. He stated that "...talk in a way that satisfies one demand, decide in a way that satisfies another, and supply products in a way that satisfies a third" (Brunsson, 1989). Organized hypocrisy is characterized not by a separation or decoupling of norms and actions. He sees it as a special case of coupling, a reverse coupling, in which organizational talk and decisions compensate for inconsistent action. Decoupling can be seen as a conscious strategy by the management, where one create two functioning levels, talk and action, one deals with the values and the other production and efficiency.

> *When institutional norms fail to agree with the requirements for action, organizations will often try to create two sets of structures and processes, one for each type of norm. These sets should not interfere with one another, but should be separated or 'decoupled.' (Brunsson, 1989)*

Brunsson sees hypocrisy as a solution rather than a problem. Decoupling talk and action enables organization to manage and operate under conflicting demands in their environment. Hypocrisy is thus not a negative but a necessary. Organizational recipes often gain a reputation for increased efficiency. Brunsson view is that formal adoption of a recipe mainly contributes to the legitimacy of the organization. To increase efficiency changes need to happen on the production level. Therefore if an organizational recipe contradicts or inhibits

production, we are faced with conflicting goals and decoupling will occur to encompass the organizational recipe. To summarize according to Brunsson I might expect to find:

- Stronger focus on the external effects rather then internal changes
- If inconsistent/conflicting demands or organizational goals, then decoupling can be used as a conscious strategy
- Strong references towards legitimacy, little references towards efficiency
- Superficial adaptation or passive implementation
- A view of the standards as predefined set of actions

3.4.2.2 Røvik

Røvik sees organizational recipes as a set of ideas that give a lot of room for translation and change. Thus the organization throughout the period of implementation can translate the organizational recipe to fit their setting. The concept of the idea is to some degree always general and thus evolves in the meeting with new challenges and environmental situations. The institutionalized recipes that can be observed as a trend is often not concrete given standards but a set of general ideas, unless we point to specific technical standards (Røvik, 1998). When organizations incorporate institutionalized standards it can give legitimacy for the surroundings. But it also has consequences for the organizations view of it self. It establishes perceptions; of which one is similar to and would like to identify with. In such a way the adoption of popular organizational recipes influence the organizational identity. Thus creating a profile for how one is in the organizational population. Loosely coupled structures or decoupling are according to Røvik a result of the multi standard organization as a byproduct. Organizations incorporate new structures and practices to accommodate the demands of their environment and consist therefore of loosely coupled structures that are employed at some time and then dropped when a new structure is more appropriate (Røvik 1996; 1998). Stakeholders anticipate that organizations incorporate new structures that are fashionable for the display of their proactive and futuristic activities (Røvik, 1998). Rørvik views decoupling as a phenomenon that occurs as a result of translation, where the adaptation inside the organization only is partial due to the inconsistent organizational recipes.
To summarize according to Røvik I might expect to find:

- Local translation of ideas in the standard to fit local problems
- Adaptation to local setting and complexity
- Focus on the organizational identity
- If inconsistent organizational recipes, then decoupling as a byproduct

4 Case studies

I will now present the data from the interviews - as three case studies. The objective is to give a concentrated presentation of the data, here under motivation, couplings and effect of choosing to commence a ISO 9001:2000 certification of the quality system.

4.1 Akershus University hospital commencing on ISO 9001:2000 certification

4.1.1 The history of quality initiatives

Akershus University hospital health trust has had quality initiatives on the agenda for a long time. Like most hospitals in Norway TQM-inspired initiatives were started in the early 90´s. In 1996 the hospital established an organizational unit to enable quality initiatives in the organization. The unit had personnel that aided and guided departments in both organization wide initiatives and local projects. The employees received internal courses and there was an effort to use flow and Pareto diagrams, other quality theories and approaches. The hospital initially decided to use the European Foundation for Quality Management Excellence Model (EFQM) and not the ISO standard as basis for the quality work. The first model did not yield much excitement in the organization according to my sources and was initially not received well by the professionals, and slowly it died as the managerial commitment for it also faded.

4.1.2 The new Ahus

The hospital is now undergoing a major change, it is moving into new facilities and at the simultaneous reorganizing. To handle the multiple projects for the new organization a project organization has been formed outside the line. One of these projects is the quality project which has become set in charge of developing and aiding implementation of a system that can lead to certification for the entire hospital after the ISO 9001:2000 standard. The initial plan was for the hospital to have such a system in place by June 2006. The concept behind the system was revised from functions to patient pathways during the autumn of 2006. The main arguments for this change in approach were gain in standardization of admission routines and the fact that the patients moved throughout the hospital. The quality system at the hospital level is at the moment (spring 2007) planned to be up and running after the physical move to the new facilities. Most departments are in the process of starting the work of building a

internal control system based on the ISO 9001:2000, some are in the process of development and only one department is certified, and another department is accredited.

The new hospital entail a laboratory center, based on the four medical service departments, with a common leadership. The departments going into the laboratory center are medical biochemistry, immunology and transfusion medicine, medical microbiology and pathology. The new center structure will seek to use analysis across the field of laboratory traditions where this is beneficial, giving a larger scientific base and more efficient use of equipment. In the overall hospital organization the laboratory center is a gathering of many medical service departments demanding much coordination to function efficiently a across the field of clinical departments. The laboratory center is to use the ISO standard in its quality work, and thus need to bring all units up to speed on this subject.

4.1.3 ISO 9001:2000 at Akershus University hospital trust

The overall process of building a quality system based on ISO 9001:2000 at Akershus University hospital trust has so far been staggering and slow. The projects organization has had a hard time getting ISO on the agenda. The initial functional approach was left for a process approach. This means going from a unit focus towards a focus on the pathway of the patients, through the hospital. The new approach is advocated by the project as better -to cope with shifting organizational structures and would be based on standardization of checking in, sending routines, inter organizational ordering/booking and check out of patients. The same goes for services and products delivered vertically through out the hospital. This becomes a much more top down process then the initial functional approach. The departments are internally having a standardization process tailor made to serve the needs there. The quote underneath illustrates how the approach has changed from the departments and functions there to the rote the patient take throughout the hospital.

> *.. we have turned a little on our approach and switched focus to the processes, the patients go through the hospital and the processes must be the same. That means that we are going from a functional approach to a process approach..*

The change in approach is argued to be better fit to the situation. And be able to sustain and cope with the changing internal structures the organization is to see in the near future. The goal of getting the entire hospital certified, entails the collectively use of the quality system throughout the hospital. This put clear demands of standardization of procedures and routines. The organization is to undergo multiple projects leading to alter organizational structure as

well as new surroundings. A quality system needs to withstand such activities and be unaffected by local changes. In a way the quality system needs to be immune towards change in the organization. The new process approach is believed to have the desired abilities. The focus in this approach is vertically between the departments, leaving the local scene to the department to administer. There has been much talk, but little action to promote and adapt the ISO 9001:2000 standard in the organization. The project organization has been somewhat left without backing and as projects have been competing for attention, resources and priority the ISO project has ended up becoming less of a priority. The development of local teams and cross department resource groups is now under way. Some efforts picked up during the period of time the data was gathered, but the project clearly bear signs of competing interest and projects, subsequently the decision has been made to be ready for certification after the move to the new facilities.

4.2 The ISO certified department of immunology and transfusion medicine

The department of immunology and transfusion medicine also known as the blood bank was certified on the 1 of March 2005 after the ISO 9001:2000. It is structured as an autonomous department with 4 doctors, 26 bio-engineers, and 4 part time health secretaries. It originally separated out of the department for clinical chemistry over two decades ago. Today it has four sub units: unit for blood donations and production of blood products, blood typological laboratory, immunological laboratory and unit for patient handling.

4.2.1 Deciding on ISO 9001:2000

The department of immunology and transfusion medicine initiated the process some four years earlier; it can be described as an early adopter if we compare it to the other departments at the hospital. In the organizational field other blood banks was at the same time initiating similar projects. The decision to adopt ISO was at that time made by the director of the department of immunology and transfusion medicine, a medical doctor. The accounts of the first mentioning of the system refer to an external consultant that had helped other blood banks to become certified. External effects of the ISO certification were a prominent part of the motivation for the endeavor of becoming certified.

> *(the director).. Decided that we should be certified… and decided to accept an offer from an external consultant that had been a consultant for other blood banks that then had been certified. And we thought it would be beneficial for us to have a certificate to show externally I believe.*

Accounts going across the level from top to bottom emphasized the external aspects of certification. The perception at the department was that this was something everyone in the organization field did. The management pointed to their participation in international conferences and stated that these had been important in deciding to go for ISO certification. The need for recognition also played a vital role, as being ISO certified seemingly was synonymous with being leading in the field. The quotes underneath illustrate how the perception on the ISO standard and the quality system was throughout the levels at the department, most accounts was strongly linked to external factors.

> *... it seems like all laboratories and institutions shall be certified in one way or the other.*

> *Blood banks in Europe have gone through certification. It is probably due to the fact that we have attended many international conferences that we have gotten it spoon feed that we needed to do this.*

> *...we thought it could be good for us to have a certificate to show externally ..*

The accounts on motivation for starting the ISO certification process was also linked to the belief that it could make the work more secure, and result in higher quality services but this seemingly came second to the external effects. The desire to manage the many demands the department was faced with was pointed to as another important aspect in why they decided to start the process.

4.2.2 Introducing the quality system at the department

There where descriptions on initial resistance towards changing procedures and the workload of which the quality system demanded. The informants at the department of immunology and transfusion medicine described different stages of perception towards the ISO standard, going from resistance to compliance. The main workload was in the beginning done by the management, the rest of the department perceived the process as something for the management. The legitimacy for the organizational recipe was low at the department and the introduction was mainly based on a hierarchical top down process.

> *(In the beginning)..on that stage it was mostly the management and the ones in more senior positions that where involved. The rest of us did not rally understand what the point of it all was.. .. We felt no excitement towards it and where generally skeptical.*

The process took more time than they initially had planned. Much work went into developing the quality system and it drained the human resources as it tied up workers, resulting in higher pressure on the remaining workers. This increase in pressure resulted

in that corners were cut in the new routines and the work was conducted as it had been before just adjusting for the documentation demands. Some of the regulatory demands were seemingly not directly reflected in the quality system. This is illustrated by the following quote on describing how informants perceived that the department could have been certified earlier, without all the demands in place.

> *We could have become certified earlier than we where. We could have, but than it were all the things that weren't in order. We could not risk to be certified, and then if the health supervision agency came we could have lost our GMP (Good Manufacturing Practice) license.*

Informants described a clear change in that procedures were written and systemized, but that the behavior not necessarily complied according to the standards. One of the main features pointed to in the phase of implementation was less manpower due to the work with the quality system.

4.2.3 The ISO certified quality system

I did not try to conduct an evaluation of the effects the quality system had on quality or any other concrete entity, but rather described the perception the informants had of the effects. Accounts the informants have made on the effects of the quality system differed. How the informants perceived the effects tended to be closely linked to the position the informant held. Frequently better structure and better overview was brought up. This was toned down by comments stating that the operational activity had become more complex, rigid and that there was an excessive amount of procedures. Informants in the management reported a reduction in the interval of variance and also easier tracing of the errors that did occur.

> *Less things slip, simply because you have the documents in place and you have to follow through.*

On the other hand there where clear doubt from other informants if the quality system yielded any benefit at all to the outcome. This argument was largely based on the amount of resources the system demanded compared to the benefits. Some informants also doubted if any positive production effect could be traced back to it at all.

> *If the patients in the end benefits from it I am a little doubtful about. This is again linked to that we are not given additional resources and that it is a demanding system so it will maybe take time away from the patient on some level.*

Other effects mentioned were better procedures, easier training of new staff, better continuity on cleaning of apparatus and easier access to information due to registration and

documentation. There are few clear references towards increased production efficiency; some support an increase in safety.

The department of immunology and transfusion medicine is the only certified department and has had almost two years of experience with the system. The informants recalled that when the certification process finally started they where going to get something back for their efforts. The impact and consequences the quality system has had on the daily activities are according to the informants quite demanding. Because of to many procedures, checklists and such that dictate in detail the work. The informants described a need for flexibility and that some things differed between the procedures and practice.

> *..besides the procedures there are many such systems where you have check points and such, something that probably is beneficial and so.. but maybe.. well… are a little demanding to keep up with in the everyday work situation.*

Given that the ISO standard was translated locally, some elements were toned down because there were too many demands. The every day work was by the informants described as more rigid and less flexible. There were by the informants at the floor references to the need for flexibility. Other accounts pointed to the fact that there at times had been differences between what had been perceived from the management to be in order, and what was really the case.

> *There is a gap between what were uttered by the management to be in order and what we did have in order…*

The actual behavior was under the quality system were described as pragmatic and flexible, seeing the quality system as a tool to aide their workday and not to dictate it. Several informants pointed to the need for flexibility between the actual behavior and the demands of the quality system. Other indicated that the economic pressure to increase efficiency, and the quality system demands seem to be somewhat inconsistent with one another. The quality system resulted in a seemingly increased transparency; this was referred to as a positive side since everyone now could observe how many and how complicated their tasks is.

4.3 Introducing the ISO 9001:2000 standard at the department of microbiology

The department of microbiology has existed for 25 years, after being split out of the department for clinical chemistry. It is structured as an autonomous department with 6 doctors, 23 bio-engineers, 3 technicians and 4 persons in the office staff. Today it has four

sections; section for bacteriology, section for infection immunology, section for substrate production and section for genetic technology.

4.3.1 Introducing a standardized quality system

The department has had a document system and quality system made locally, but they where displeased with it. The department of microbiology has for over two years been in the process of developing a quality system based on the ISO standard. The department started to work with the ISO standard after receiving signals from the hospital administration that this was a long-term goal. These signals given from the hospital was described as strategic visions, many other departments did not initiate to the same degree to start the work towards certification.

The department of microbiology had described an initial phase of resistance based on arguments along the lines of " why " and "do we need this". As the leadership effort fell into a period of remiss and transition, subsequently the quality manager substituted as head of the department. This phase gave a better foothold and simultaneously the bio-engineers increased the interest in the system and advocated full adaptation. Informants stated that the newfound interest from the bio-engineers at the microbiological department was primarily based on a perception of trend of this sort of efforts. Further also the increasingly competitive market they faced as well as the upcoming merge into the laboratory center. The informants also claimed that the project organization had halted the initiative for certification, through statements on collective certification in the new laboratory center. Motivation for building the quality system was pointed to being both linked to practical efficiency in the work situation at the department and the potential external effects.

The increasing competition the department is faced with came as private providers and other public labs increasingly competed in getting in external test. Demands in the environment was pointed to by the informants to be increasingly linked to quality and thus the fact that "everyone else" was implementing the ISO standard was also a major part of the motivation the bio-engineers had for pushing for adoption. That the quality system would be more effective in achieving higher quality services was not emphasized much by the informants. The focus was rather emphasized on the fact that it would make the workday easier and structured the demands the department faced making them easier to handle. The standard was

also believed to have consequences for the marked position of the departments. The quote under illustrates these aspects.

> *...Not necessary that it would be much more effective, but I think it would give a better workday. More secure since we know where we can find the things we need and so on. Also the competitive aspects have been considered important. We know private actors are entering...*

The fact that Ullevål university hospital health trust has a identical but much larger department and that they might be merged had been discussed, but not given much real weight. Then again being certified would result in a trade of between quality and economies of scale. The informants discussed the demands the department was faced whit and they felt there was a dual axis of both for better quality and higher efficiency. The quote underneath illustrates how the perception of the ISO standard was at the department. They saw it as something coming back and being evermore in demand from external actors.

> *It was a period where it was a little like everyone should be accredited, I have a feeling it is coming a little bit back again. But it has also been an aspect in the whole thing that politicians demand ever-stricter efficiency goals and then it can result in more competition for the customers and then certification may become an advantage.*

The fact that a increasing number of similar departments in Norway and in Europe is certified was also pointed out as an important factor to why they were so eager to get started with the process of ISO certification.

4.3.2 Getting the system in place

The department of microbiology is not yet certified. The process has been going on for more than two years. The commitment to implement the ISO standard is seemingly lacking from the management. However the laggard implementation can be ascribed to a set of reasons. High turn over in the top management, lack of long term commitment and general lack of cross professional collaboration. The process was described as spread periods of spurs in quality work. Also the competence was raised as a major question, there were not many sources of obtaining the information one needed for facing the different set of questions one faced at the different stages, thus one ended up with improvised local strategies for building the system. The informants indicated that they had started in the wrong end of things, doing what was easiest, writing out the procedures. The structural elements of the system at the managerial level had not been in worked whit continuously and as a effect the it took a long time to get it up and running.

The overall hospital process has to some extent held the process back as they have been waiting for the hospital routines to be established. The process seemingly also had little cross professional support, or more explicit the lack of support from the medical doctors. This fact halted and possibly hindered the process as procedures where not approved, checklists and subsystems not being established.

> *We have chosen to put it on a level where the medical doctors must approve the procedures and they have every thing else to do so they rarely have time to really go through them and if they first do they discover that the procedures are not good enough in relation to what they want. So we have had many rounds with many procedures back and forth.*

The informants referred to that over time the bio-engineers learned more about the ISO standards and a switch happening from the management demanding the system and promoting it to the bio-engineers demanding more efforts and promoting the system. The initially threatening demands manifesting by the ISO certification process were by the professional group increasingly seen as compatible with other goals the professionals had. They became actively involved and through this involvement, managed to influence and take advantage of the system potentially negatively correlated whit autonomy and leading to increasing transparency. They recognized the potential certification had both internally and externally, and sought to influence and possibly control it rather then the other way around. The prospects of a quality system became for the bio-engineers point of view something positive, that might yield benefits in the objective outcome; quality, as well as respond to ever increasing regulatory demands, market exposure and strengthening their professional position.

5 Discussion

5.1 Understanding why organizations adopt the ISO standard

Motivation can be described as the reason or reasons one has for acting or behaving in a particular way, thus motivation is the reasons behind the decision to adopt. There might be a wide set of different reasons, some based on conscious decisions others more emerging as a result of chance or contextual historic reasons leading to a window of opportunity. Addressing and investigating motivation ex post faces a methodological challenge as the subjects often mirror the result in the initial motivation.

5.1.1 ISO 9001:2000 a rationalized myth

The ISO 9001: 2000 standard fit the description of a rationalized myth. This is illustrated by the fact that it is to a large degree taken for granted by the informants and presented as the "best practice". Rationalized myths have a dynamic of their own in translating facts and reality into myths. This could be observed as all respondents referred to it as an efficient way of improving quality of service, but could not point to any direct effect on quality. The establishment of ISO quality systems cannot be explained by evidence of their effectiveness or superior ability to increase quality, since such evidence is scarce (see Kunnskapssentret, 2006).

The organizational structure can be seen as a set of rationalized myth that the leaders of the organization compose together to achieve the needed production related traits desired and the legitimacy needed to operate in the environment (Meyer & Rowan, 1991). The Norwegian public hospitals are operating in an environment where there traditionally has been a high degree of trust towards public organizations. Normative pressure is applied from several strong professional groups ant their organizations, an increasing number of user organizations and the media. The environment the hospitals are faced whit have increasingly become complex. The informants pointed to this as they described ever-increasing pressure for efficiency as well as the described focus on quality. Two entities that the informants at the hospital level described at best only partially coinciding. The environment has seen an increase in patient organizations, higher media focus and a high political attention. Pressure from rationalized myths in the institutional environment can be diffuse and conflicting, in the cases the efficiency and quality illustrate this. But also the quality focus in it self can be

conflicting as case is when the professionals out of a professional are related to the processes related to delivering a intervention, while the patients out of a user logic relates quality to their overall experience were communication and appearances is just as important or more than the significance level of a test.

5.1.2 Demands and signals in the environment

New institutional theory can be useful in investigating why an increasing number of healthcare organizations are engaging in ISO certification. Important in this regard is the signals in the environment, new national strategies, conferences and a general increase in references towards quality of care both by politicians and by the new regional health authorities. A key point here is the new organizational structure as it has made an irreparable brake with spoken and unspoken historic political priorities of the local demographic pattern. This brake is being fronted by a balanced set of arguments based on efficiency and quality. The quality arguments is thus not only used, as a medical numbers need argumentation, it is also a part of a broad front of quality focus. Quality is in fashion, in fashion because it is an important for both patients as well as health care professionals, it fits with the trend for larger hospitals due to medical specialization and economic reasoning and because it damps the political turbulence of the geographical disputes. Thus organizational recipes linked to quality are in demand in the environment. The ISO standard has a reputation built in other sectors than health, and thus it breaks the stalemate of the interest groups, rendering the health professionals left intangibly unable to maneuver away. This was the case at the department of immunology and transfusion medicine as the managerial level saw the benefits of transparency, programming of activity and ability to manage the regulatory demands. The result of the managerial infatuation was a top- down implementation without much local support. Comparative reputation is valuable, resulting in managerial introduction, decisions being made, and talk being produced.

5.1.3 Isomorphism

The motivation to engage in certification after the ISO standard was ascribed to strategic decisions for the development of the hospital as well as signals and compliance to decisions by the regional health authority east. Akershus university hospital health trust has motivation linked to corrective isomorphism and need for legitimacy. The traditional status of Akershus university hospital as a hospital just at the breaking point between a central hospital and a university hospital can also explain some of the motivation to commence on as ISO process.

As a traditional production hospital the move towards quality is not just theoretically favorable based on the distribution of patients but also strategically favorable in an increasingly competitive environment. The introduction of free choice of provider for the patient makes the situation for the elective treatments much higher as the hospital is competing for patients in a geographical area where the density of hospitals is high -relative to other areas in the country. Much of the corrective element stems from the signals from the regional health authority east describing ISO 9001:2000 as a vital part of quality efforts in the region. Thus compliance whit such signals might be a significant part of the decision by Akershus University hospital to adopt the ISO 9001:2000 standard.

Much of the motivation to engage in ISO certification process for the department of immunology and transfusion medicine can be argued to be rooted in mimicking isomorphism. Mimicking isomorphism is when you due to perception of a complex situation, seek to adopt a solution other organizations in the field have adopted, thus it is in fact copying. Many similar departments of immunology and transfusion medicine throughout the country and in Europe were engaged in ISO processes or was accredited or certified at the time they initiated their process. The leadership at the department frequented at conferences and accounts state that after a conference the initial talk about building a quality system based on ISO 9001:2000 came up, this is pointed to in the first quote under 4.2.1.

For the department of microbiology the motivation can be traced from initially corrective isomorphism to the hospitals decision to adopt ISO 9001:200. A switch occurs to a normative isomorphism, as the bio-engineers aligned the ISO standard with their professional norms and goals of professional recognition and receives signals from peers about the potentially harmful effects it might have if left up to others to implement and decide over.

5.1.4 Other environmental factors

In a comparative perspective the story from the private sector around the world is that the organizations engaging in building a quality system based on ISO often are well-established companies. They often find themselves in a situation where their competitive advantage in terms of growth is narrowing. The overall results from the private sector are that certification provides positive results (Brown and van der Wiele, 1996 and Buttle, 1997). Taking a closer look on the cause of the alleged effects, presents clear differences among various researchers. Lee (1998) and Idris *et al*. (1996) find that internal effects such as reduction of scrap, rework

and seconds were the most common effects, while others claim that market related benefits are the dominant effects (Buttle, 1997). In any case the effects described are at first glance not directly transferable to a Norwegian public hospital setting. However the situation is quite transferable for some of the laboratory departments that are increasingly faced with competition both by private actors and somewhat by each other. Thus as the marked leaders in the private sector they are up against a situation where their competitive advantage is narrowing as the prices are being pushed down. Informants at the department of microbiology commented on how the situation was becoming more competitive and that they needed to signal the strengths a university hospital had in competence. The ISO certification thus can be an effort to remain in their position by signaling superior performance on quality, seeking to even out the price effect in the marked, by differentiating their product.

5.1.5 Moving from efficiency toward legitimacy reasons for adoption

The accounts from the informants on motivation to adopt in the three cases differed little in that both legitimacy and efficiency of the standard to deliver the desired outcome was mentioned. What did differ, was the balance between the two, and what the desired outcome entailed. The department of immunology and transfusion medicine empathized the efficiency of the standard to increase quality to a much higher degree than the department of microbiology. Illustrated in the first quote under 4.3.1 the desired outcome of the quality system was an easier workday at the department contrasting quality of the service and end product pointed to by the management at the department of immunology and transfusion medicine. The department of microbiology gave significantly fewer references towards efficiency overall. Again going to the quote illustrated under point 4.3.1. the efficiency towards increasing the quality was not the main objective. The objective was the internal needs of the departments in regards to getting a better working process at the department. Furthermore informants at both of the departments emphasized a desire for legitimacy from external actors and the environment. The adoption by the department of immunology and transfusion medicine was more related to performance, while they both emphasized legitimacy. The data suggests that the early adopter puts a greater emphasis on efficiency compared to the later adopter, this based on the considerably lower focus on efficiency to improve quality by the later adopter. This might be due to the fact that overtime the ISO have gained strength and function as a rationalized myth and that the superior performance of achieving quality is taken for granted. Only one department actually has a up, running and certified quality system, but the motivation to start a ISO 9001:2000 certification process

seemingly did go from efficiency to legitimacy reasons over time. This might be due to mimicking isomorphism were the desire to reduce potential differences between the one how have adopted and the own uncertainty in achieving the desired outcome decide to copy solutions from other organizations. This might explain why I found much higher degree of legitimacy related argumentation for adoption at the department of microbiology, non the less legitimacy is increasingly important in the decision process to become certified after the ISO 9001:2000 standard.

5.2 The department of immunology and transfusion medicine

5.2.1 Adoption of the organizational recipe

At the department of immunology and transfusion medicine the informants described a clear top down process. Where they viewed the process as something the management worked a lot with and which they to a little degree contributed in constructing. This is illustrated by the quote under 4.2.2. There were several accounts of the scepticism towards the ISO standard. They where given tasks and came through according to those, but did not feel that they grasped the full extent of the system. The informants at the department of immunology and transfusion medicine support a variation of perceptions on legitimacy and in the belief of capability of the organizational recipe to deliver according to the goal function, mostly in the early phases of adoption. Furthermore there was also a perception of that the outcome of the organizational recipe is not aligned with other organizational goals. Some also saw the organizational recipe as somewhat incompatible with their daily work; especially the need for flexibility due to the complex and shifting nature of their work -was pointed out. The reaction and behavior at the department of immunology and transfusion medicine was to a large degree consistent with the most of the excepted resistance towards change presented under 3.4.1. The top-down process at the department combined with the low legitimacy of the ISO standard in the early phases of adoption and a perception that the outcome of the organizational recipe was not aligned with other organizational goals, resulted in a decupling between structure and behavior. This answered to the need for legitimacy, improving some aspects of efficiency; of delivering high quality services and decoupling elements hindering the production efficiency.

5.2.2 Formal and actual organizational procedures

The predictions made about what characteristics and mechanisms decoupling might have according to Brunsson and Røvik differ. The main difference between the two is at the point of why decoupling might take place. Brunsson state that the core element is inconsistent and or conflicting organizational goals, and that decoupling then happens as a conscious strategy. Røvik claim that due to the multi-standard organization, if one incorporate inconsistent organizational recipes it might result in decoupling as a byproduct. The immunological department gave accounts of the quality system conflicting with the drive for efficiency.

> *..besides the procedures there are many such systems where you have check points and such, something that probably is beneficial and so.. but maybe.. well… are a little demanding to keep up with in the everyday work situation.*

Different accounts pointed in the same direction as the quote above that the demanding new system was separated from the work done and that there was pragmatic attitude towards it. My interpretation of the accounts is that there is a conflict or at least a contradiction between the goal of the quality system and the goal objective of efficiency. It did not find enough support as to state that organizational members view the quality system more along the line of an obstacle to performing their work, but neither strong support for it being of any important aid in the production core except systemizing procedures if one needed to look one up. There seemingly where a larger conflict on the allocation of resources rather than a conflict between the goal objectives of efficiency and quality. Informants pointed out that the quality system took resources from production and slowed the entire process down. There where accounts supporting an effort to minimize the impact the quality system had on their daily work processes. The end result of behavior seemingly was more a result of things becoming to rigid than a conscious decision to decouple the quality system. The department needs to satisfy the requirements from the hospital, regional and national authorities and those of the certifying body. That is why they had to change their behavior, introduce the elements of the standard and rather limit the impact in the every day activity.

There was similarities to Brunsson's term of organizational hypocrisy, where members try to achieve conflicting goals, both convince upper management of their loyalty to the quality system, and at the same time proceed protecting the efficiency of their established work processes. This manifests as a formal adoption, but limited impact of the recipe. I did find some seemingly conflicting goals and strong indications on a decupling between the

organizational recipe and the actual activity. In regard to superficial adaptation or passive implementation, I found little indication for the adaptation being a concert for the external certification body as the system is in place. However the informants described the stamina of the system in everyday use to fluctuate according to constraints. There had been significant fitting and adoption to the local settings at the department.

Røvik pointed out how organizational recipes are vague set of ideas that are translated locally in to something that then diverge from the similar adoption in other organizations. There where several accounts supporting a local translation of the ISO 9001:2000 standard. The ISO standard is a system generic recipe stating key components and mechanisms for constructing a quality system. The informants from department of immunology and transfusion medicine described a process of fitting the standard together with their organizational reality and specifying desired functionality. The standard translation was conducted mainly by the managerial level, while tasks was delegated and delivered to specs on the production level. I could not identify any contradicting organizational recipes that could give grounds for decoupling between system and behavior. The informants pointed out a process of initially trying to copy elements directly and seeing the ISO process as a predefined set of actions. After figuring out that this was not effective a process a long the lines of translation as described by Røvik took place. This fits with the description of the ISO standard as a set of ideas that needs to be adapted to the local setting. The certification process provided some homogenization of system features. Having a system in tact, certified and in use did however not directly result in a change of behavior. As described earlier there were indications of a decoupling of system and behavior. Decoupling is however not necessarily a negative feature, in this case it came as a solution. By acting according to certain norms and logics, and mirroring compliance to other norms and logics one managed maintaining legitimacy and shield the production efficiency.

5.2.3 Legitimacy

At low levels in the department of immunology and transfusion medicine the discussions was primarily linked to pragmatic and normative aspects, questioning if the new organizational recipe would yield the effects of higher quality. This is illustrated by the second quote under 4.3.2 here the informants describe how they perceived the standard as low in regard to achieving the goal of higher quality. I see this as an example on how low legitimacy the ISO standard had internally at the production level in at the department. Legitimacy seems to

influence the degree of coupling between system and behavior. Here the decoupling could be traced back to the changes initially having low legitimacy among the ground workers and the change strategy chosen by the managerial level.

5.2.4 Development over time

The bio-engineers over time realized that the organizational recipe could be compatible with their professional norms, values and could be aligned with their professional goals. Their professional goals of recognition, status and provider role of high quality services were increasingly seen as compatible with the ISO standard and its reputation.

Implementation at the department of immunology and transfusion medicine was lead from the top, and the changes, measures and problems were defined through the organizational recipe. This resulted in many interpretations of why it was introduced and what the main goal was. Over time the alignment with normative professional logic resulted in an environment of change that encompassed the quality system and increased the coupling between system and behavior both due to an increased belief in the efficiency of the system but also as one noticed that one could use the system to promote the profession, local reputation and in making the demands in their workday easier to cope whit.

5.3 The department of microbiology

At the department of microbiology the informants pointed out some initial skepticism towards the standard. There was a considerable time difference (3-4 years) between when the two departments initiated their work on constructing a quality system. At the department of microbiology there was a significant difference between talk and action. There was some support of a decoupling between talk and action but this was more a result of the rotation in management then a conscious decision.

5.3.1 A shift from top down to bottom up

Pollitt (1990) stated that a profession's control of its own work, especially with regards to how the work is assessed and evaluated, is central to professional authority and independence and by partially the reason for the skepticism. As the normative isomorphism gained strength as ground for motivation, the behavior changed for the bio-engineers. They started to demand the quality system based on the ISO standard being given more focus. The bio-

engineers became actively engaged in the work of creating procedures, and building the basis for a quality system. As the professionals learned more about the ISO standard and peer signals confirmed the ISO systems ability, they sought to utilize initially threatening external demands to their own advantage. The approach where the bio-engineers started with producing procedures and then presenting them for ratification by the medical doctors is seemingly not optimal. Procedures kept getting rejected based on arguments that they where inadequate. This seems a little ironic since the procedures reflected the way things was done at that point in time, ergo the standard and thus quality was to low. A more tangible reason was rather that the medical doctors failed to realize the procedures as the starting point, in the process and not the end result. Thus the medical doctors saw the quality system as a radical innovation and not an incremental improvement. This was likely a result of their professional logic and attitude rooted in the medical doctors perception of the ISO system as a transparency effort and thus inherent skepticism towards it.

Hersvik and Nesheim (1995) pointed out that quality management initiatives in the public sector have been found to enhance the emphasis on efficiency-based control of employees, despite the rhetoric of employee empowerment and learning. Even with certification resulting in potential control and continuous external inspection of professional practice, the bio-engineers at the department of microbiology realized that the external pressure for the system was high and thus controlling the evaluation criteria and the processes by active participation would be the best strategy.

The expected findings of resistance towards change did not manifest at the department of microbiology beyond an initial brief skepticism. The local setting was at the department of microbiology more complex and shifted from an initial resistance to becoming a bottom-up pressure to work with putting the system together. The bio-engineers present accounts of internalization and alignment of desire for professional recognition and commitment to increase quality. The quality work was halted by lack of cross professional foundation and further also changing regimes at the top level of the department.

5.3.2 Towards a professional rather than managerial system

The ISO standard has a procedural and technical character that one thus can expect to be especially alluring for one of the professional groups at the medical service division, the bio-engineers. The demand in the environment for quality initiatives seemingly has increased

over the last couple of years. Both the organization and the professionals within the organization needed legitimacy, and the ISO standard can provide that. The department of microbiology faced conflicting professional rationales and lack of managerial stability rater than conflicting organizational goals.

There are many ways professionals can react to introduction of an organizational recipe, only some might result in decupling. There was little indication of decoupling between system and behavior, at the department of microbiology as the main driving force and initiative over time was sustained from the bottom. The accounts where split into a top-down account of events for the department of immunology and transfusion medicine and a peculiar top-down, flip, bottom-up situation for the department of microbiology. The professional group of bio-engineers became actively involved in the development and use of the ISO standard system, but use the system for the needs they had then and there without necessarily realizing externally defined goals such as quality of service and product. This undermines the instrumental view of the organization to conform to central governments and authority's goals and point to the new institutional argument that the departments and or groups in the department will use the implications of the change efforts for their own needs or resist it if not fitting. This can be described as a decoupling between the organizational recipe and adoption. Situations like the one at the department of microbiology is by Røvik addressed when he states that decoupling can occur in the translation process as no organization has the same set of organizational recipes and thus it is impossible to exactly replicate a organizational recipe across organizations. The outset of internal control is to produce a higher quality end product and answerer to all demands. The quality system became more about organizing the ground workers need for a system of the demands then meeting the demands in to the production. This was illustrated by the first quote under 4.3.1 of introduction of the quality system at the department of microbiology. Here the purpose of getting a more organized workday was pointed to, and not necessarily that it would yield any quality gain, but rather make the workday easier.

The medical service departments have both different professional compositions and operational activities then other types of departments at a hospital. How the organizational recipe will be meet by other departments with different composition and type of work can't be generalized from this study. I strongly emphasize the relationship between the "technical"

nature of the work and the involved professional groups and culture up to comparison against the pattern observed and described.

5.4 Decoupling between talk and action at Akershus university hospital

The informant on the hospital level was located in the project organization. Few accounts pointed to direct conflicting goals, rather more competing goals. There were references to a significant difference between talk and action, most on the account of being highly ambitious talk and almost no action. This can be explained by the complex change situation and the fact that the quality system was composed of both local initiatives as well as project initiatives and needed a holistic strategy, which took a long time to agree upon. Further it needed to compete for attention both at the top level and at the department level, the fact that no extra resources came with the initiative further also resulted in a low priority. Some accounts indicate the translation capacity of the organization was near its maximum and thus a decoupling between the talk and action was a reaction to this. This since many of the organizational recipes applied in the organization where conflicting in time with the ISO initiative. One example is the new laboratory center, where the organizational change would result in a in a blend of organizational units and procedures on all levels of implementing ISO standard levels. The project organization faced many possible organizational changes and organizational recipes that contradict the effort of constructing a hospital wide quality system, the change in approach can be seen as a reaction seeking to strengthening the coupling between the ISO standard translation and the organizational structures. A generic intersectional approach was the hospital wide systems thus become more immune to change and interference from other organizational recipes and can be seen as an adaptation to local setting and complexity. The decoupling between talk and action can also be a conscious decision as the talk has value in it self and doing little - fitted the strategic plan of the overall hospital change.

5.5 The fragile balance of logics and rationalities

An organization faced whit many change processes, reform efforts and goal perceptions might disturb the fragile balance between different logics and rationalities. In the cases of the two departments the ISO standard was introduced out of a managerial logic, resisted by different professional logics and as a result being translated in to something edible for both

parts, and subsequently being at the department of microbiology promoted whit in a professional logic. The question if the organizational recipe was the "same " as the one advocated initially by the management is a subject for discussion. So if the quality system certified after the ISO standard changed character, the reputation and perception changed over time or if the external demands resulted in the ISO standard becoming "logical" for all parts is a difficult to answer precisely. For the three cases presented in this thesis there was most likely a combination.

5.5.1 Introduction through managerial logic and blossoming rooted in a professional logic

An organizational recipe is general set of ideas about how one is to structure an organization (Røvik, 1998). In the case of the ISO standard this holds true, as it is a set of eight generic ideas on how to construct and operate a quality system. It relies on local fitting and translation. During this process at the department of immunology and transfusion medicine the standard was aligned whit the managerial logic and rationality, and in the adoption process there was a failure to make it compatible whit the logic of the different professional groups, opting for hierarchical power to implement it instead of broad support. This was illustrated by the accounts stating that the management made a decision and then they worked whit it for a long time not including the ground workers, making them skeptical and suspicious of the intent of the new system. The result was a decoupling of system and behavior, this due to the conflicting goal functions of quality and efficiency, the low legitimacy and the fact that it did not fit the logic of the different professional groups. Over time the certified quality system was embraced by at least the professional logic of the bio-engineers, again a result both rooted in legitimacy as well as the efficient ability the system had for reaching the goals of the professional group.

At the department of microbiology the system and outcome abilities was introduced and rooted in a managerial logic. Over time the management succeeded in sparking an interest and advocating it based on a professional logic. The management did however fail to follow the process through and controlling the objective of the system, the quality system based on the ISO standard was then seemingly "hijacked" by the bio-engineers. The bio-engineers faced normative pressure and had a desire for legitimacy rooted in a professional logic, as well as being faced whit a increasing competitive market and signals from the hospital and the regional health authority east. The findings resemble the case described by Robelet (2001) were new accreditation programs seem to be a threat to the medical doctors professional

autonomy by controlling the core activities. Here less powerful segments of the medical profession managed to reposition themself in a competitive environment by getting actively involved in the elaboration of new quality assurance manuals. Thus if the rationalized myth has a strong foothold it is better to seek to control, steer and manipulate it than to fighting it.

5.5.2 Towards a stronger managerial position

The mangers do often neither have the access or the knowledge to control compliance and the professional groups lack the resources, power and hierarchical position to implement, thus a agency situation arises. I argue that signals coming from the bottom (read: the professional groups) are easier aligned whit managerial logics than the other way around, this due to the traditional "soft" line between management and professionals in the management at Norwegian hospitals. Being that there is no traditional managerial profession and that the main continuance of hospital mangers is health care professionals. The result being a grater emphasis put on professional logics than on the managerial logic, making it for managers easier to steer the organization through their original professional logic. This argument fit whit statements that initiatives of change at hospitals traditionally come from the bottom. The neoliberal reform wave pressured in higher focus on the professional managers (read: mangers trained in management, economics and law), as well as marked mechanisms and other private sector treats, resulting in higher exposure to rationalized myths, as well as a more demanding environment result in higher frequency of change efforts being rooted in a managerial logic. Also managers in the new environment observe that legitimacy needs no longer is sufficiently met through just the traditional claims of the professionals. This trend is reinforced by the entry and strengthened position of yet another logic: the user logic. Subsequently an alliance across managerial and user logics has been made. And not only in terms of efficiency as has been the case since health care expenditure spiraled out of control as early back as in the 70´s, but now also in regard to quality. Thus there is a conflict between the ability to impose changes in the organization and formal position, as the mangers now seek to gain legitimacy throughout imposing organizational myths not justified out of a professional logic, the result might resemble the case of the department of immunology and transfusion medicine were a decoupling between system and behavior occurs. For the department of microbiology the approach was to aligning the changes whit the professional logic, resulting in an altered or partial adaptation. Over time one can argue that the balance between the professional and managerial logics are recognized through accepting the outcome of stalemate one reaches as one are working against one another. Also contributing

is the strong democratic logic inherent in Norwegian labor law. It can be discussed if decoupling of the system and behavior was intended from the managers, given the strong ties to the professional logics or if the resulting decoupling is a result of to little power. In any case rationalized myths persuade or seduce all members of society and translate reality and facts in to a mindset that is the basis for the myth. As a result of this, professional groups over time will be influenced and subsequently transform their perception accordingly if it fits whit their main values. Even initially threatening reforms and systems can then be aligned whit professional goals or be translated in to less threatening versions and promoted. This was the case for the department of microbiology as the professionals both realized the external advantages as well as the potential hazardous effects, resulting in a coup d'état of the entire initiative of constructing a quality system according to the ISO 9001:2000 standard.

5.5.3 Resource demanding adoption

The establishment of the quality system was by both departments described as resource demanding and by the department of immunology and transfusion medicine also resource demanding in every day use. The organization should evaluate if the sum of perceived efficiency and legitimacy is worth the cost, especially given the suggestions of new institutional theory of organized recipes having a relatively short life span. The hospital is not giving any extra funding. The accounts by the informants indicate that the implementation might even reduce efficiency. If the result is a trade of between quality and efficiency, one needs an assessment of the effect of certification in regard to quality as well as the descriptions of legitimacy given in this thesis to be able to make a rational decision. Then again maybe the decision to act as they did were rational in their situation, at least the informants seem to think so.

5.6 Towards changing supervision system

The board of health was by all informants pointed out as one of the recipients of the signal effect of ISO certification. The informants all pointed out that they where less likely to receive supervision when they where certified, this then represented a move towards a voluntary annual inspection of the quality system by an external private organization. Supervision seemed to be something that had potential negative outcome, being cited for lacking system ability or adverse events were described by the informants as having negative effect on reputation, both for the organization but also for the employees in the professional

sphere. Thus a voluntary system of certification both increases the system ability but also the perceived likelihood of supervision. There are a tendency for privatization of supervision in the health care sector, it is not grand but could be increasing. Supervising pharmacists for the municipal health services have in some places been put out on the marked and have been provided by the lowest bidder among the pharmacy corporations. This scenario is highly unlikely for the board of health due to the regulatory manifestation. However a shift from "dyadic" to "triadic" supervision relationship, where the board of health supervise the health organizations as well as review the reports and practices of the private certification organizations, similar to the inspections and supervisions in the Norwegian petroleum industry can be the result of wide spread or mandatory certification.

5.7 Certification and accreditation as a quality approach in Norwegian health care

The number of actors having regulatory demands and supervision with the laboratory departments especially and the health sector is generally vast. The regulations and demands faced by the laboratory departments are complex and overlapping. Participation in external reviews becomes less and less voluntary by signals and actions taken by the regional health authority east and seemingly soft regulation turns into required practice. In Denmark a mandatory certification regime is in place. The consultant report on the regional health authority's functionality by Agenda and Muusmann of November 2005 recommends the establishment of a national or regional mandatory certification system. This advice has to be seen in the light of the authors experience from Denmark. Contradicting this recommendation is that no evidence supports the Danish model as of today. The tradition for use of regulations in Norway must be taken into account; certification is traditionally advocated by nations having far less regulations of the health sector. To supply highly quality and safe health services new approaches must be taken into consideration, however I strongly recommend gathering better knowledge on the effects of certification before commencing on a path towards mandatory certification.

The regional health authority east has pointed out ISO 9001:2000 as being a key element in quality efforts within the region. Emphasis is put on the fact that the regulatory demand of internal control originally was based on the ISO standard. In this regard one state that going to the source of the regulation, one can better understand and comply with the regulation and achieve the intended result. The difference between internal control and a quality system is

small. This is then a way of promoting the ISO standard despite the highly regulated environment the organization is in. The answer to compliance with regulation thus becomes voluntary certification. It is somewhat of a paradox that the ISO standard is most spread and popular in nations that do not have detailed health regulation, and we who have it, in order to comply whit it, need certification. Informants at the departments described how the knowledge about internal control and other regulations often was sparsely disunited. They described how a quality system could systemize the regulatory demands and enlighten the departments on the methodology on how to comply with them, in this way the organization benefited from it. This point to knowledge being the enabling factor and thus educational programs might yield in effects on quality just as good results as certification, but then again part of the legitimacy element and the effect planed external supervision has, regardless of being the board of health or a private actor, would be lost.

6 Conclusion

My analysis suggests that an institutional perspective provides an important complement to the instrumental perspective. The study has been on the adoption of ISO 9001:2000 at Akershus university hospital and the findings suggests the decision to commence on this path had both efficiency and legitimacy reasons. The process of ISO certification has beside increasing quality of care, a function to communicate information about the organization to both internal and external actors. The decision to adopt the ISO 9001:2000 signal a consistent value set between the organization and the environment, hence to the uttered values in society. Public organizations face a completely different composition of demands in the environment. While a private organization face the consumer and the spheres interfering with the profit function and gain legitimacy as long as profits are maid. The public organization face a more complex environment, consistent of a wide set of interest, from the supervision authority to the regular patient. I have in this thesis provided an analytic perspective describing and given some explanations for why an increasing number of health care organizations are commencing to construct and certify quality systems according to the ISO 9001:2000 standard. I have illustrated how legitimacy is becoming increasingly important and that managers in public organizations both seek efficiency and legitimacy through their actions.

I identified the main obstacle in measuring the effects of the ISO certified quality system in the health care sector, to be the fact that there is no commensurable unit for measuring something from not happening. The effect one measure is therefore random occurrences of multi causality, deviant human biology and a categorized interval of adverse events. Effect assessments are difficult, but non-the less as more and more resources are used on ISO certification processes better effect studies are needed to guide public decision-making.

The question if the quality system actually is effective in increasing quality has been shown by the informants to be a secondary one. Organizational success is by the informants linked to other factors than efficient coordination and control of production activities. The informants described the subjects in this study all seeking to become isomorphic with the environment and gain the legitimacy and subsequently resources, positions and reputation needed to

survive. The belief in the efficiency of ISO 9001:2000 to increase quality differ, but nonetheless it is viewed as serving a useful purposes in other regards.

New institutional theory provided valuable insight in analyzing and understanding the reactions towards change initiatives. Medical service departments face new demands that might result in a reorganized department structure, common technology structure, as well as an increasingly competitive market. Traditionally laboratory department have some of the highest quality level of all departments across health care services, this being a result of both the character of the work and an the culture. Given these characteristics it is not that surprising that these departments pioneer the adoption of quality systems built after the ISO 9001:2000 standard. The organizational recipe was at the two departments adopted and resulted in a change of behavior, some of the characteristics from one of the departments bore similarities to the concept of decoupling as described by Mayer and Rowan (1977).

A theoretical conclusion from the study is that the potential a reform or organizational recipe has to change the behavior, culture and identity of an organization depends on the way it fits whit the existing norms and values, as well as the ability it has to be rationalized in the logics of a wide enough powerbase of actors. If a organizational recipe conflict whit the rationalities and logics of one of the groups of actors, as in the case of the department of immunology and transfusion medicine, then the effect might be resistance, pragmatic compliance and decoupling.

A secondary theoretical conclusion is that instrumental and new institutional perspectives can benefit of being seen not as divided by a dichotomy but as having the largest explanatory ability if they are viewed as overlapping. A closer relationship could yield theoretical concepts and explanations that are less elegant, but more realistic. Furthermore it might lead us to avoid generalizations that subsequently can give a deeper understanding of what we do and why we do it.

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